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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,033	09/09/2003	Wuhan Jingya Xu	27300/04C1CIP	3295

7590 10/23/2006  
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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/659,033	XU, WUHAN JINGYA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

### DETAILED ACTION

Claims 1-15 are pending in the instant application.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,441,025 or US 5,977,163 or US 6,262,107, each one of them assigned to Li et al. US 6,441,025 has been used in explaining the rejection below.

Li teaches water-soluble drug compositions formed by conjugating a drug to a water-soluble polymer conjugate. The compositions are used for the treatment of tumors, autoimmune disorders and arthritis (abstract, col. 3, lines 5-32). Li teaches conjugating various types of drugs, including the claimed anti-tumor drugs (col. 3, lines 31-43). Li also teaches conjugating drugs with the polymer for improving solubility of the drugs, reducing systemic toxicity and improving the therapeutic index of the drugs (col. 3, lines 60-63). Thus, the teachings of Li meet the limitations of the instant claims. Among the polymer conjugates, Li teaches polyglutamic acid (for instance, figures 7A-7E and 14) and poly-aspartic acid, poly-lysine and mixtures of glutamic and aspartic or lysine residues (col. 8, lines 28-45). Further, Li also teaches both d- and l- forms of amino acids, in the polymers and thus meet the limitation of claims 6, 35 and 72. Li teaches that the polymers may comprise combinations of natural or modified or unusual amino

Art Unit: 1615

acids as long as the majority of residues i.e., greater than 50% comprise glutamic acid and/or aspartic acid and/or lysine (col. 8, lines 47-55). Further, Li teaches the various percentages of glutamic acid, aspartic acid, lysine and other amino acids that comprise higher and lower limits of conjugates (col. 9, lines 1-35). The molecular weights of polymers described by Li in col. 5, lines 26-59, fall with the claimed range. While Li does not specifically use a mixture of glutamic acid and aspartic acid or glutamic acid in combination with the claimed second amino acids (aspartic acid, arginine, glutamine etc.) and in particular in the claimed percentages, Li teaches the polypeptide or polyamino acid carrier for the same purposes i.e., as a carrier for drugs, for improving the therapeutic index and the solubility of drugs. Further, Li suggests various percentages of glutamic acid, aspartic acid and lysine, either as homopolymers or as mixtures of glutamic acid and aspartic acid and/or lysine, as carriers for several types of drugs, which includes the claimed drugs. In particular, Li teaches that the carrier primarily contains greater than 50% glutamic acid. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use mixtures of glutamic acid and aspartic acid as a carrier for the drugs, in particular, anti-tumor drugs, because Li teaches that the polypeptide carriers when conjugated to the drugs, overcome the drawbacks associated with insolubility of drugs (col. 10, lines 19-22), treat any cancer (col. 6, lines 40-53), improve the therapeutic index of the drugs and reduce systemic toxicity of chemotherapeutic drugs (col. 3, lines 60-65). Further, it would have been obvious for one of an ordinary skill in the art to optimize the percentages of individual amino acids in the polypeptide with an expectation to achieve

Art Unit: 1615

the desired solubility and therapeutic index, depending on the drug used and the condition being treated.

***Claim Rejections - 35 USC § 112***

Claims 12, 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claim recites a method of treating a condition, without specifying the condition. The claim employs paclitaxel for the treating the condition. However, the claimed drug is only known for cancer treatment and not for any other condition. Instant specification does not describe any other condition that the compound may be used for. Further, instant claims also fails to state that the condition is responsive to paclitaxel treatment. Accordingly, the instant claims fails to meet the written description requirement.

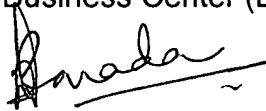
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone

Art Unit: 1615

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Lakshmi S Channavajjala', with a horizontal line drawn underneath it.

Lakshmi S Channavajjala  
Examiner  
Art Unit 1615

October 16, 2006